

**Department of Health and Human Services  
National Institutes of Health**

**National Center for Advancing Translational Sciences Advisory Council  
and  
Cures Acceleration Network Review Board**

**Minutes of Joint Meeting  
January 12, 2017**

The National Center for Advancing Translational Sciences (NCATS) Advisory Council and the Cures Acceleration Network (CAN) Review Board held a joint meeting in open session on Jan. 12, 2017, convening at 8:30 a.m. ET, in Conference Room 10, Building 31, on the National Institutes of Health (NIH) main campus. Christopher P. Austin, M.D., NCATS Advisory Council chair, and Freda C. Lewis-Hall, M.D., CAN Review Board chair, led the meeting. In accordance with Public Law 92-463, the session was open to the public.

Following the joint meeting, the NCATS Advisory Council met in closed session for the review and consideration of grant applications.

**NCATS ADVISORY COUNCIL MEMBERS PRESENT**

***Chair***

Christopher P. Austin, M.D., Director, NCATS

***Executive Secretary***

Anna L. Ramsey-Ewing, Ph.D., Director, Office of Grants Management and Scientific Review, NCATS

***Council Members***

Margaret A. Anderson, M.A.

Jorge L. Contreras, J.D.

Geoffrey S. Ginsburg, M.D., Ph.D.

Daniel L. Hartman, M.D. (by telephone)

Eric D. Kodish, M.D.

Freda C. Lewis-Hall, M.D.

Bernard H. Munos, M.B.A.

Alan D. Palkowitz, Ph.D.

Harry P. Selker, M.D., M.S.P.H.

Anantha Shekhar, M.D., Ph.D.

Scott J. Weir, Pharm.D., Ph.D. (by telephone)

***Representative Members***

None present

***Ad Hoc Members***

Ronald J. Bartek, Friedreich's Ataxia Research Alliance

Katharine Ku, M.S., Stanford University

Richard E. Kuntz, M.D., Medtronic, Inc.

Geoffrey Shiu Fei Ling, M.D., Ph.D., Uniformed Services University of the Health Sciences

Brad Margus, Cerevance, Inc.

G. Lynn Marks, M.D., GlaxoSmithKline

Valerie Montgomery Rice, M.D., Morehouse School of Medicine

Todd B. Sherer, Ph.D., Michael J. Fox Foundation for Parkinson's Research

Stephen P. Spielberg, M.D., Ph.D., Therapeutic Innovation & Regulatory Science

**Ex Officio Members**

David Atkins, M.D., M.P.H., Department of Veterans Affairs  
S. Rao Kosaraju, Ph.D., National Science Foundation  
Frank F. Weichold, M.D., Ph.D., Food and Drug Administration (representative for Commissioner Robert M. Califf, M.D.)

**CAN REVIEW BOARD MEMBERS PRESENT**

**Chair**

Freda C. Lewis-Hall, M.D., Executive Vice President and Chief Medical Officer, Pfizer

**Vice Chair**

Geoffrey S. Ginsburg, M.D., Ph.D., Director, Center for Applied Genomics & Precision Medicine, Duke University School of Medicine; Professor of Medicine and Pathology, Duke University Medical Center; and Professor of Biomedical Engineering, Pratt School of Engineering, Duke University

**Executive Secretary**

Anna L. Ramsey-Ewing, Ph.D., Director, Office of Grants Management and Scientific Review, NCATS

**Board Members**

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Jorge L. Contreras, J.D.	Harry P. Selker, M.D., M.S.P.H.
Daniel L. Hartman, M.D. (by telephone)	Anantha Shekhar, M.D., Ph.D.
Eric D. Kodish, M.D.	Scott J. Weir, Pharm.D., Ph.D. (by telephone)
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**OTHERS PRESENT**

NCATS leadership and staff  
Dane R. Christiansen, M.B.A., Health and Medicine Counsel of Washington  
Stephen Heinig, M.A., Association of American Medical Colleges  
Bryan Patterson, M.P.A., CFCM, CF APMP, Rho, Inc.  
Julie Vick, CCRP, Rho, Inc.  
Nancy Yovetich, Ph.D., Rho, Inc.

## **I. CALL TO ORDER**

Christopher P. Austin, M.D., and Freda C. Lewis-Hall, M.D., called the meeting to order. Dr. Austin welcomed members and guests to the 14th meeting of the NCATS Advisory Council and the 18th meeting of the CAN Review Board. He reminded attendees that the open session was being videocast. Dr. Austin introduced the *ad hoc* members of the Advisory Council and the CAN Review Board.

## **II. CONSIDERATION OF MINUTES: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, NCATS Advisory Council and CAN Review Board**

The minutes of the joint meeting held on Sept. 15, 2016, were approved as written. Anna L. Ramsey-Ewing, Ph.D., informed the group that the NCATS Advisory Council and CAN Review Board will have joint meetings in 2017 on May 4 and Sept. 7. The 2018 meetings will take place on Jan. 11, May 10 and Sept. 27. The CAN Review Board also will meet by teleconference on Dec. 15, 2017, and Dec. 14, 2018.

## **III. CONSIDERATION OF OPERATING PROCEDURES: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, NCATS Advisory Council and CAN Review Board**

The council operating procedures were approved as written.

## **IV. INTRODUCTION OF NEW STAFF**

- B. Duane Price, Ph.D., is the deputy director in the Office of Grants Management and Scientific Review and a former senior scientific review officer at the National Institute of Allergy and Infectious Diseases. His doctorate is in genetics.
- Dobrila D. Rudnicki, Ph.D., is a program officer in the Office of Special Initiatives.
- Kenneth R. Gersing, M.D., is the director of informatics in the Division of Clinical Innovation (DCI) and has become a federal employee after almost a year as a contractor. He is a psychiatrist.
- Anne R. Pariser, M.D., is the deputy director of the Office of Rare Diseases Research (ORDR). She worked on rare diseases and translational sciences at the Food and Drug Administration (FDA). She is a board-certified internist.
- Rebekah E. Geiger, M.S.W., is the chief of the Ethics and Management Analysis Branch in the Office of Administrative Management.
- Samuel G. Michael is the chief of the Information Technology Research Branch and chief information officer for NCATS. He was recognized in 2012 as the NIH Federal Engineer of the Year.
- Ann R. Knebel, Ph.D., RN, FAAN, is the deputy scientific director of the Division of Pre-Clinical Innovation. She has a background in nursing research.

## **V. DIRECTOR'S REPORT: Christopher P. Austin, M.D., Director, NCATS**

Each Advisory Council and CAN Review Board member received an electronic summary of NCATS activities. Any member who wishes to have a paper copy can request one before each meeting.

The planned guest speakers, Eric Dishman, director of the *All of Us* Research Program, and Matthew Might, Ph.D., University of Utah, were unable to attend.

Christopher P. Austin, M.D., thanked the retiring members of the Advisory Council and CAN Review Board:

- Freda C. Lewis-Hall, M.D.
- Geoffrey S. Ginsburg, M.D., Ph.D.

- Margaret A. Anderson, M.A.
- Robert J. Beall, Ph.D. (absent)
- Jorge L. Contreras, J.D.
- Louis J. DeGennaro, Ph.D. (absent)
- Eric D. Kodish, M.D.
- Ankit A. Mahadevia, M.D., M.B.A. (absent)
- Bernard H. Munos, M.B.A.
- Robert I. Tepper, M.D. (absent)
- Scott J. Weir, Pharm.D., Ph.D.

Dr. Austin welcomed new members:

- Daniel L. Hartman, M.D., Bill & Melinda Gates Foundation
- Megan O'Boyle, Phelan-McDermid Syndrome Data Network (absent)
- Alan D. Palkowitz, Ph.D., Lilly Research Laboratories

### Policy and Legislative Updates

- **NCATS Strategic Plan.** NCATS released its strategic plan on Nov. 29, 2016. The plan sets out a vision for the field of translational science. NCATS' role is as a catalyst. Most translational roadblocks are generic, so understanding the general principles of translational medicine can help produce progress for many diseases. The goal is not incremental change; the goal is dramatic improvements in efficiency. To that end, NCATS is committed to measuring effectiveness of its programs. Successful translation requires working in teams across the spectrum of science, which can be challenging. The ultimate constituents of NCATS are the patients.
- **Fiscal Year (FY) 2017 budget.** The FY 2017 President's Budget Request was released Feb. 9, 2016. NCATS' request was \$685.417 million, the same as for FY 2016. FY 2017 began Oct. 1, 2016, and the government has been operating since then on a continuing resolution that extends FY 2016 levels of funding. For the remainder of FY 2017, it is not yet known whether Congress will pass a budget or whether it will continue to fund the government with continuing resolutions.
- **21st Century Cures Act.** The President signed this bill on Dec. 13, 2016. Some key provisions are that it:
  - Exempts NIH research from the Paperwork Reduction Act.
  - Exempts NIH from conference and travel requirements that made it difficult for scientists to attend conferences.
  - Requires the Office of Management and Budget to establish a research policy board that will review regulations, with the goal of relieving the administrative burden for extramural researchers.
  - Requires NIH consider ways to reduce the burden on grantees related to sub-recipient monitoring and animal care and use.
  - Includes provisions related to data access and privacy, including a requirement to issue Certificates of Confidentiality.
  - Authorizes the NIH Director to require funding recipients to share data. This is especially important for NCATS, which needs to look for commonalities across many studies.
- **Legislative Implementation Work Group.** Whenever a statute is passed with implications for NIH, a working group is established to go over the statute and determine how NIH will implement each of the directives.

## Year in Review — FY 2016

- **Evolution of the NCATS solicitation ecosystem.** Over the past five years, the number of solicitations has greatly increased, while the NCATS budget has remained nearly flat. NCATS' programs have evolved as the Center has learned how the programs can be more effective. As these programs have become more complex, with more elements, NCATS has put out more solicitations. Writing these solicitations increases the workload for NCATS. Finding independent peer reviewers also has become more difficult. The NCATS FY 2016 budget of \$684 million is in the middle of the range of budgets for NIH Institutes and Centers (ICs). The majority of the NCATS budget (just under \$500 million) is allocated to DCI programs.
- **Evolution of the Clinical and Translational Science Awards (CTSA) Program.** The CTSA Program evolved from a single solicitation and award mechanism, the legacy Funding Opportunity Announcement (FOA). After the Institute of Medicine issued its report on the CTSA Program in 2013, NCATS made some changes and now has an ongoing CTSA Program announcement with three receipt dates per year.
- **Structure of the CTSA Program.** The CTSA Program has three components: a research and infrastructure component and two training components. The CTSA Program also includes innovation networks for clinical trials and recruitment, administrative supplements for enhancing network capacity, and infrastructure to support the increasingly complex program, including a coordinating center. These changes have advanced the science being supported through the CTSA Program. Dr. Austin shared a list of FY 2016 awardees for these components. Most awards were to major research institutions.

### *Discussion*

Geoffrey Shiu Fei Ling, M.D., Ph.D., asked how a startup would fit into the CTSA Program. Philip John (P.J.) Brooks, Ph.D., lead program director for the CTSA Program, said there are opportunities for collaborations, and NCATS encourages interaction between startups.

Valerie Montgomery Rice, M.D., noted that many of the awards go to the same institutions. Some smaller institutions are partnering with research-intensive institutions, but more should be done to engage these institutions and their communities. This is also a challenge for other parts of NIH.

Dr. Austin said some of the most innovative thinking comes from smaller institutions, but larger institutions tend to have the resources and grant-writing experience that impress peer reviewers. This is a constant source of frustration for NCATS.

Petra Kaufmann, M.D., M.Sc., director of DCI and the Office of Rare Diseases Research (ORDR), said this is a constant tension. NCATS wants the best science for everyone, but it can't happen in only a few institutions. The review branch has recruited experts in community engagement. She welcomed input.

Dr. Rice said NCATS should be bold and require inclusion of smaller institutions.

Dr. Austin said the NCATS Small Business Innovation Research (SBIR) program is a success story.

Dr. Ling said that NCATS' own scientists should be given more autonomy and authority over decisions. He has found that this worked well at the Department of Defense. The private sector should also be

involved. “Good science” is not the goal; it is a given that the science will be good. The goal is cures and therapies.

Todd Sherer, Ph.D., asked how NCATS is ensuring consistency with respect to rules and regulations, now that the CTSA Program uses many funding mechanisms.

Dr. Kaufmann said this is the challenge of a complex network, and NCATS is working on it now. There are two directions. One is collaborative innovation awards, for which investigators propose innovations that are ready for a demonstration project across multiple sites. The other comes from NCATS and previous investigators through the steering committee. This increasing complexity has led NCATS to create more network capacity. The Trial Innovation Centers are an example of this. Metrics are part of the answer.

Dr. Austin said program staff work has shifted. They formerly worked with individual centers on meeting their own goals, but now that the network is much more complicated, they have to think about the whole network. Program staff also are more involved in the science.

#### **Year in Review — FY 2016, Continued**

- **Evolution of the Discovering New Therapeutic Uses for Existing Molecules (New Therapeutic Uses) program.** Through its New Therapeutic Uses program, NCATS partners with pharmaceutical companies to find new indications for existing drugs. Like the CTSA Program, the New Therapeutic Uses program originally had a less complicated structure. It was later updated to include research on pediatric drugs, and now it also has a planning component to fund planning for trials. This change was implemented based on data about the success of the program. For example, NCATS added New Therapeutic Uses bench-to-clinic initiatives to help test drugs that were identified by computational algorithms. If these algorithms work, they may be useful for many drugs.
- **Driving awareness of the SBIR/Small Business Technology Transfer (STTR) programs.** The SBIR/STTR programs are the vehicles by which NCATS interacts most directly with the biotechnology startup community. When NCATS was a new IC, SBIR/STTR applicants were not aware of the program and the types of applications that the Center wished to fund. The current outreach initiative is to increase awareness of these NCATS programs, particularly among women- and minority-owned small businesses. This is expected to continue to increase the number of high-quality applications and advance small business innovation. NCATS is continuing to reach out through new partner channels and interact with potential applicants through webinars, conferences, one-on-one meetings and direct email. The focus is on priority audiences, such as women- and minority-owned businesses. NCATS also has strengthened relationships with historically black colleges and universities and has a strong SBIR/STTR presence via social media.
- **Interest in the SBIR/STTR programs.** Surveys after webinars have shown that attendees are interested in the SBIR/STTR programs. The number of applications per year continues to increase. The average score of SBIR/STTR applications has decreased, indicating an increase in the quality of applications. A lower score represents a higher-quality application.
- **NCATS’ SBIR/STTR awardees gaining recognition.** Recursion Pharmaceuticals, an NCATS SBIR awardee, is using clustered regularly interspaced short palindromic repeats to create disease models based on induced pluripotent stem cells that can be used for testing drugs. The NCATS plate washing initiative, led by IonField Systems, is saving money and keeping plastic out of landfills. NCATS awardee AiCure has developed a smartphone application that confirms medication ingestion to address compliance and adherence challenges.

- **Key NCATS achievements:**
  - Increased quantity and quality of applications, with more applications coming directly to NCATS.
  - Increased social media education and engagement.
  - Increased targeted engagement with women researchers and entrepreneurs.
  - Increased SBIR leadership engagement with potential applicants.
  - Increased awareness of, interest in and applications to the NCATS SBIR and STTR programs.

### ***Discussion***

Dr. Kodish asked whether NCATS' continued existence is secure.

Dr. Austin said this was a concern early on, but over the past five years, NCATS has transformed itself from a poorly understood outsider to a highly respected driver of innovation. When Dr. Austin visits Capitol Hill, the people he talks to are enthusiastic and understand what NCATS is doing. Five years ago, policymakers did not understand what translational science was or why an IC was needed to study it.

Dr. Rice said the way that NCATS has reviewed and restructured itself is refreshing. She acknowledged NCATS' core founding group for their work and said she expects to see NCATS evolve more in the future under the Center's current leadership. She encouraged NCATS to be inclusive and to continue to look for good ideas in surprising places.

Stephen P. Spielberg, M.D., Ph.D., noted that he has filed five successful supplemental New Drug applications for pediatric labeling for drugs that were already on the market. The patients in the trials were not being enrolled by high-profile institutions. Less prominent institutions can conduct high-quality trials. NCATS needs to think broadly about how to engage with different institutions, not only those institutions supported through the CTSA Program. NCATS may be able to play a role in improving the paradigms for pediatric clinical trials. For example, there are currently 17 products for diabetes that are ready for pediatric trials, but no one is recruiting. NCATS can also help improve the process for converting a molecule into a product for rare diseases. The FDA is interested in different ways of doing this research. NCATS could help by considering topics such as different types of clinical trials, adaptive trials and Bayesian statistics.

Ronald J. Bartek asked how other ICs view NCATS, given the importance of trans-NIH collaboration.

Dr. Austin said that NIH colleagues initially were curious about NCATS but worried that it would not be a team player. NCATS won them over by explaining that the Center is helping them conduct disease-related research at a higher level by focusing on translational questions that are different from and complementary to their questions. It is difficult to overcome NIH's tradition of separation among the ICs. Each IC gets its own line item from Congress, and the ICs are not used to collaborating. NCATS has begun to change this.

Harry Selker, M.D., M.S.P.H., gave his perspective as an extramural collaborator for several years. He noted that there has been a cultural revolution in the science community in the last 10 to 20 years. NCATS has helped make that happen and has made a big difference outside of NIH.

## **VI. CAN REVIEW BOARD UPDATE**

Instead of a traditional update, Freda C. Lewis-Hall, M.D., invited the members of the NCATS Advisory Council and CAN Review Board to share opportunities to move forward, lessons learned from the last five years, and key programs about which they are enthusiastic.

Geoffrey S. Ginsburg, M.D., Ph.D., said more could be done to optimize the use of the Other Transaction Authority (OTA) funding mechanism. The ability to match NCATS-CAN funds with partners also could be exercised. Partner opportunities should be optimized. He also noted that innovations are happening not only in science but also in policy. He thanked Dr. Lewis-Hall for her five years as chair of the CAN Review Board.

Margaret A. Anderson, M.A., agreed that OTA should be used more often because NCATS is secure now and can take more risks. She also said that NCATS should do more to communicate its work and should do more with public-private partnerships. Industry also should be advocating for more funding for NIH. Finally, NCATS should work more with basic science.

Pamela M. McInnes, D.D.S., M.Sc.(Dent.), deputy director of NCATS, noted that using OTA also requires the appropriation of funds. Having the authority does not necessarily mean having the money.

Bernard H. Munos, M.B.A., said the system has many biases built into it — for example, against young scientists and smaller institutions. It favors people who know how to write grants because the process is somewhat complicated. The only questions that matter are, “Is the scientific foundation sound?” and, “If it is successful, will it change something?” The concurrence process is particularly dysfunctional. Also, Mr. Munos said that NCATS should have a way to stop funding a project if someone else answers the research question partway through. The Defense Advanced Research Projects Agency can do this, and it makes sense not to spend more money on a problem that is already solved.

Scott J. Weir, Pharm.D., Ph.D., said NCATS should be very proud of the team effort that re-engineered the CTSA Program. He encouraged the incoming Advisory Council members to help NCATS look for new opportunities in areas such as big data, health care delivery models and devices now that the CTSA Program is on a solid path. He also suggested the Advisory Council help NCATS drive policy changes — for example, by creating incentives for finding new uses for existing drugs.

Dr. McInnes responded to Mr. Munos’ point about cutting off funding for a problem that has been solved. With OTA, there is no promise for future funding, and managers are actively involved.

Christopher P. Austin, M.D., said this very effective management style could be applied to other programs.

Harry Selker, M.D., M.S.P.H., said NCATS should be friendlier to basic science and work on the entire process of product development.

Jorge Contreras, J.D., urged NCATS to more systematically fund research on ethical, legal and social implications. Questions to study would include how to streamline the process of complying with all of the rules and regulations related to research; how to make the regulatory process more efficient and how it compares to other countries; how cooperative research and development agreements and other cooperative agreements would work — for example, by learning from experience with public funding of semiconductors; and how intellectual property could be pooled among companies.



Eric D. Kodish, M.D., said that NCATS could play an important role in advancing the science of informed consent.

Anantha Shekhar, M.D., Ph.D., said that NCATS can change the model for research in its role as an incubator. In addition, the Centers for Medicare & Medicaid Services should be engaged with the process at NCATS, because the end goal is to help patients.

Dr. Lewis-Hall noted that when New Therapeutic Uses was launched, it was not clear whether pharmaceutical and biotechnology companies would take part, but they have. In addition to OTA, NCATS should find other ways of innovating with help from technical and other experts. Finally, she said, this discussion is about delivering *Star Wars* medicine into a *Flintstones*-era health care system. Programs should reach all the way to the patient.

**VII. UPDATE FROM THE OFFICE OF RARE DISEASES RESEARCH: Petra Kaufmann, M.D., M.Sc., Director, Office of Rare Diseases Research and Division of Clinical Innovation, NCATS**

Petra Kaufmann, M.D., M.Sc., provided an update on NCATS' ORDR. Each rare disease affects only a few patients and is being investigated by only a few investigators. But because there are so many rare diseases, 25 million people in the U.S. are probably affected. Most patients are undiagnosed, and fewer than 500 rare diseases have treatments.

NCATS can make a difference in advancing rare diseases research by partnering with patients, academics and industry; leveraging technology; creating a research continuum; and engaging the next generation of researchers. This is team science, which is very different from how many scientists were trained.

One way to accelerate the path from discovery to health benefits is by integrating clinical care and research. Another way is to work with the rare disease registries that already exist and help patient groups create new ones. Although rare disease registries collect data, the data often are not exactly the information required for the regulatory pathway, so industry has to start over. Data standards could help maximize the value of every data point.

Some of the investigative groups in the Rare Diseases Clinical Research Network (RDCRN) partner with industry, and ORDR staff have talked about how to share experiences and best practices. NCATS' ORDR also has set up the Trans-NIH Rare Diseases Working Group, which meets quarterly. Many rare diseases affect multiple organs and organ systems, so it is important to partner with colleagues at ICs that focus on particular diseases or organ systems.

Dr. Kaufmann reviewed current ORDR programs:

- The NCATS Genetic and Rare Diseases Information Center is an online resource for the public that offers information on rare diseases in both English and Spanish. It has contact information for telephone queries to genetic counselors and physicians.
- The NIH/NCATS Global Rare Diseases Patient Registry Data Repository program has made common data elements and informed consent templates that all registries can use. NCATS can be a catalyst, giving groups tools to set up their own registries that can work like natural history studies, rather than simply contact registries.
- The RDCRN includes 22 consortia, each focused on a group of diseases related by organ, mechanism or symptoms. For each consortium, NCATS partners with the NIH IC that works in

that space. The data management is centralized. The RDCRN has more than 90 active protocols and includes a training component.

- NCATS is developing a rare diseases toolkit to help more patients get involved in translational research. The toolkit will link to existing resources, including patient organization sites.
- NCATS works with international partners because both investigators and patients are rare. This coordination has included a collaboration between those representing NCATS' New Therapeutic Uses program and the E-Rare initiative in Europe.

In the future, NCATS hopes to increase ORDR collaborations with other NCATS programs and continue to move from working on one disease at a time to a more holistic approach. Partnerships are very important for rare diseases, and the RDCRN should help clarify best practices for ethics and conflicts of interest. NCATS also would like to be a catalyst in the exciting area of gene therapy and gene editing for rare diseases.

### ***Discussion***

Geoffrey S. Ginsburg, M.D., Ph.D., asked about the relationship between ORDR programs and the Undiagnosed Diseases Network (UDN). Dr. Kaufmann said that ORDR staff work closely with UDN staff. Dr. Ginsburg asked whether NCATS could take a leadership role on the data structure for an international common variant database. Dr. Kaufmann agreed that this is a problem and said that ORDR staff are part of a collaboration with the Global Alliance for Genomics and Health that is examining data discovery. Together, they hope to be able to make it easier to look across data for different rare diseases. This is hard work that relies on trust and personal networking. NCATS would like to be a catalyst and set up processes so that rare disease research can be less siloed in the future.

Ronald J. Bartek noted that some of the programs Dr. Kaufmann talked about are already showing promise toward that goal.

Richard E. Kuntz, M.D., said that data mining with existing data can be unreliable when the practice of medicine varies widely, as it does in the U.S. It may be necessary to standardize medical practice for rare diseases. Dr. Kaufmann noted that precision medicine will make more diseases into rare diseases.

Anantha Shekhar, M.D., Ph.D., suggested that more rare disease work could be carried out through the CTSA Program.

Frank F. Weichold, M.D., Ph.D., said that NIH and other large organizations need to drive change in how data is handled. This includes examining data structure and ownership.

Stephen P. Spielberg, M.D., Ph.D., said that the success in cystic fibrosis should be repeated in other diseases. The drug ivacaftor exists because of advocacy by patients and the Cystic Fibrosis Foundation. It was a remarkable effort. The Cystic Fibrosis Foundation had many necessary elements in place, such as a network of doctors who also know how to conduct scientific research. Christopher P. Austin, M.D., said NCATS has thought a lot about how to apply this in other diseases, and the Cystic Fibrosis Foundation's unusual elements made a big difference.

### **VIII. ADJOURNMENT OF OPEN MEETING**

Christopher P. Austin, M.D., thanked all participants for their input. He and Geoffrey S. Ginsburg, M.D., Ph.D., adjourned the open portion of the meeting at 12:35 p.m. ET.

**IX. CLOSED SESSION OF NCATS ADVISORY COUNCIL**

This portion of the Advisory Council meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Advisory Council members discussed procedures and policies regarding voting and the confidentiality of application materials, committee discussions and recommendations. Members did not participate in the discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent.

**X. ADJOURNMENT OF CLOSED SESSION OF THE NCATS ADVISORY COUNCIL MEETING**

Christopher P. Austin, M.D., adjourned the closed session of the NCATS Advisory Council meeting at 1:50 p.m. ET.

**CERTIFICATION**

We hereby certify that, to the best of our knowledge, the foregoing minutes and supplements are accurate and complete.

\_\_\_\_\_  
Christopher P. Austin, M.D.  
Chair, NCATS Advisory Council  
and  
Director, National Center for Advancing Translational Sciences, NIH

\_\_\_\_\_  
Date

\_\_\_\_\_  
Anna L. Ramsey-Ewing, Ph.D.  
Executive Secretary, NCATS Advisory Council  
Executive Secretary, Cures Acceleration Network Review Board  
and  
Director, Office of Grants Management and Scientific Review, NCATS

\_\_\_\_\_  
Date

\_\_\_\_\_  
Freda C. Lewis-Hall, M.D.  
Chair, Cures Acceleration Network Review Board  
and  
Executive Vice President and Chief Medical Officer, Pfizer

\_\_\_\_\_  
Date